

Prescription Label

Patient Name:

Species:

Drug Name & Strength:

Directions (amount to give how often & for how long):

Prescribing Veterinarian's Name & Contact Information:

Refills:

[Content to be provided by prescribing veterinarian]

Florfenicol/Terbinafine/Mometasone Topical Solution

(*flohr-feh-nih-call/ter-bih-nah-feen/moh-meh-tah-zohn*)

Description:

Topical treatment for bacterial and yeast ear infections

Other Names for this Medication:

Claro[®], Simplera[®]

Common Dosage Forms:

Veterinary: Florfenicol 16.6 mg/mL, terbinafine 14.8 mg/mL, and mometasone furoate 2.2 mg/mL in 1 mL single-use dropperette

Antimicrobial Classification:

Highly Important

This information sheet does not contain all available information for this medication and has not been reviewed by FDA Center for Veterinary Medicine. This sheet can help answer commonly asked questions but is not a substitute for medical advice. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- Labeled for use in dogs to treat itching and inflammation associated with bacterial and/or yeast ear infections. Must not be used in dogs with damaged ear drums.
- Combination of antibiotic, antifungal, and steroid anti-inflammatory ingredients.
- This medication should only be administered by veterinary personnel.
- Prevent patient or other household animals from licking or grooming the area for at least 20 to 30 minutes after application.

How is this medication useful?

The FDA (U.S. Food & Drug Administration) has approved this topical solution for external use in dogs to treat inflammation in the ears caused by bacterial and yeast infections. This combination product contains an antibiotic (florfenicol), an antifungal (terbinafine), and a steroid anti-inflammatory (mometasone). You and your veterinarian can discuss why this medicine is the most appropriate choice.

What should I tell my veterinarian to see if this medication can be safely given?

Many factors might affect how well this medicine will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- Other medicines can interact with this medication, so be sure to tell your veterinarian and pharmacist what medications (including other topical medicines, vitamins, supplements, or herbal therapies) you give your animal, including the amount and time you give each.

- Tell your veterinarian about any conditions or diseases your animal may have now or has had in the past, especially diabetes mellitus and Cushing's disease.
- If your animal has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how well it did or didn't work.
- If your animal is pregnant or nursing, talk to your veterinarian about the risks of using this medicine.
- Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching, hair loss) your animal has developed in the past.

How long until I will know if this medication is working, and how long will the effects of this medication last?

This medication should help your animal feel better within 1 to 2 hours. Your animal's clinical signs should improve after that time; however, you may not see the effects of this medication outwardly. The effects of this medication are long-lived, meaning they may last for multiple (ie, 4 to 6 weeks), although they may be prolonged if your animal has decreased kidney and/or liver function.

When should this medication not be used or be used very carefully?

No medicine is 100% safe in all patients, but your veterinarian will discuss any specific concerns with you about using this medicine in your animal.

This medicine **SHOULD NOT** be used in animals:

- That are allergic to florfenicol, terbinafine, or mometasone
- With a confirmed or suspected ruptured ear drum
- That are pregnant, nursing, or used for breeding

This medicine should be used **WITH CAUTION** in patients:

- With recurring ear infections
- That have certain types of liver disease

If your animal has any of these conditions, talk to your veterinarian about the potential risks versus benefits.

What are the side effects of this medication?

Side effects that usually are not serious include:

- Redness or discomfort at the site of application

You don't have to be overly concerned if you see any of these signs unless they are severe, worsen, or continue to be a problem. Contact your veterinarian if this happens.

Side effects that may be serious or indicate a serious problem:

- Worsening or severe redness or discomfort at the site of application
- Infections that do not respond to treatment, do not appear to be healing, or are getting worse
- Loss of appetite, persistent vomiting, or diarrhea
- Sudden hearing loss
- Progressive ear pain, signaled by animal crying at contact with ear and/or head
- Head tilt or walking in circles
- Development of sores around the mouth
- Increased thirst (eg, frequent drinking of large quantities of water) and/or frequent urination

If you see any of these signs, contact your veterinarian immediately.

If my animal gets too much of this medication (an overdose), what should I do?

An overdose is unlikely to occur, as the medication is administered in the veterinary clinic. If you have any concerns, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers that are open 24 hours a day include **Pet Poison HELPLINE** (855-764-7661) and **ASPCA Animal Poison Control Center** (888-426-4435); a consultation fee is charged for these services. It is helpful to have the package instructions when calling for treatment advice.

How should this medication be given?

This medication should only be administered by veterinary personnel.

What should I do if I miss giving a dose of this medication?

This medication is usually administered as a single treatment in the veterinary clinic

How should I store this medication?

Because this medication is administered by veterinary personnel, you will not need to store this medicine at home.

Can handling this medication be hazardous to me, my family, or other animals?

- Humans with known hypersensitivity to any of the medicines found in this product should not handle it. Pregnant and nursing women should use caution when handling.
- Always wash your hands after touching your animal once the medication has been applied.
- In case of accidental ingestion by humans, contact a physician immediately.
- In case of accidental skin contact, wash area thoroughly with water.
- Avoid contact with eyes.

What other information is important for this medication?

- Do not allow your animal or other animals to scratch or lick the ears as this will delay healing and possibly introduce infection and inflammation to the area. If necessary, your veterinarian may place a collar on your animal to prevent this from happening.
- Do not clean the ears for 30 days after this medication is applied or the product may not be as effective.
- Recheck examinations are important for successful treatment of your animal's condition. Do not miss these important follow-up visits.
- This medicine contains a steroid as an anti-inflammatory, which can have effects on the rest of the body when applied to the ears.
- Use of this medicine may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.

If you have any other questions about this medication, contact your veterinarian or pharmacist.